



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

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Ms. Ona Scandurra
Director of Nutrition Communications
NBTY, Inc.
90 Orville Drive
Bohemia, New York 11716-2510

Dear Ms. Scandurra:

This is in response to your letter of February 11, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that NBTY, Inc. is making the claim identified below for products containing Glucosamine/MSM and distributed under various brand names.

The products use the claim "...is perfect for individuals experiencing minor joint aches." The statement is made in the context that the product provides dietary ingredients needed for joint cartilage formation and maintenance. The claim identified above is a disease claim because it suggests that the product is intended to treat, prevent, or mitigate diseases, namely joint disorders such as arthritis. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1016-17), FDA stated that "joint pain" is characteristic of arthritis and that it is the most sensitive physical sign of rheumatoid arthritis. For that reason, the agency concluded that claims about relieving joint pain are implied disease claims because they represent that the product will have an affect on a characteristic sign or symptom of a disease (see 21 CFR 101.93(g)(2)(ii)). Moreover, elsewhere in the preamble to the final rule (see 65 FR 1000 at 1030) FDA discussed the circumstances under which claims about pain would imply disease treatment. We stated that since pain is not a normal state, nor are there "normal pain levels," a claim about pain treatment or prevention is ordinarily a disease claim. We addressed the issue of joint pain claims in particular, noting that such claims are disease claims because joint pain is a characteristic symptom of arthritis. We added, however, that an acceptable structure/function claim could be made for pain associated with non-disease states, such as muscle pain following exercise. The claim contained in your notification does not refer to pain associated with a non-disease state.

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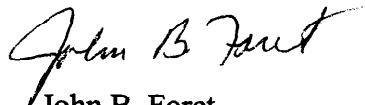
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21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for these products suggests that they are intended to treat, prevent, or mitigate diseases. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

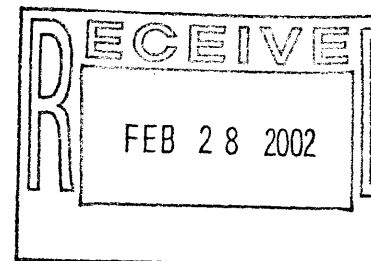
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New York District Office, Office of Compliance, HFR-NE140



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Office of Nutritional Products
Labeling & Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

February 11, 2002

Dear Sir or Madam:

This letter will serve as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 that NBTY Inc. is using the following statements on our Glucosamine/MSM supplements under one or more of the following brand names: American Health, Bioenergy Nutrients, Body Fortress, Good 'N Natural, Health's Finest, Heartland, HealthSmart Vitamins, HealthWatchers, Herbal Authority, Life's Finest, Natural Wealth, Nature's Bounty, Nutrition Headquarters, Nutrition Warehouse, PhysioLogics, Precision Engineered, Puritan's Pride, US Nutrition and Vitamin World:

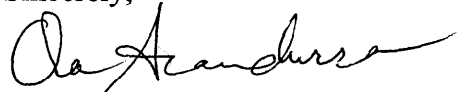
- Helps support joint cartilage.
- Methylsulfonylmethane (MSM) is an organic source of sulfur, one of the major building blocks of glycosaminoglycans.
- Glucosamine and glycosaminoglycans are key structural components in cartilage and play an important role in the maintenance of joint cartilage.
- Vitamin C is involved in collagen formation.
- Manganese-containing enzymes play a role in the production of essential cartilage compounds.
- Ginger and White Willow provide natural herbal support to this unique formulation.
- Glucosamine/MSM Complex revitalizes the cellular components within joints and is perfect for individuals experiencing minor joint aches.
- Our cartilage and joint support matrix promotes flexibility, enhances cartilage health and is the ideal joint support supplement for anyone desiring extra nutritional support.
- Scientific studies indicate that Glucosamine contributes to your support system by providing the building blocks for promoting cartilage.
- MSM contains naturally occurring bioavailable sulfur, one of the raw materials for collagen.
- Cartilage and collagen, along with other components, including water, form a web-like matrix that contributes to the strength and stability of your muscle and skeletal systems.

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- Together these elements make up the connective tissue responsible for forming the cushion between joints and bones.
- Similar to your car's shock absorbers, this cushion helps to absorb the everyday pressures put on your body's structural system.

The above statements are accompanied by the required disclaimer pursuant to Section 6 of the Dietary Supplement Health and Education Act.

Sincerely,

A handwritten signature in black ink, appearing to read 'Ona Scandurra', written in a cursive style.

Ona Scandurra, MS, RD
Director of Nutrition Communications

OS/tk